NOTICE OF PROPOSED REGULATION ADOPTION AND REPEAL

California Code of Regulations
Title 17. – Public Health
Division 4 - California Institute For Regenerative Medicine
Chapter 6

Date: December 19, 2008

Deadline for Submission of Written Comment: February 2, 2009 – 5:00 p.m.

Hearing Date: None scheduled.

Subject Matter of Proposed Amendments: Intellectual Property and Revenue Sharing Requirements for Non-Profit and For-Profit Grantees

Sections Affected:

The proposed regulations adopt Chapter 6 of Title 17 of the California Code of Regulations, and sections 100600, 100601, 100602, 100603, 100604, 100605, 100606, 100607, 100608, 100609, 100610 and 100611.

Repeal Title 17 of the California Code of Regulations, sections 100300, 100301, 100302, 100303, 100304, 100305, 100306, 100308, 100309, 100310, 100400, 100401, 100402, 100403, 100404, 100405, 100406, 100407, 100408, 100409 and 100410.

Authority: Article XXXV of the California Constitution and Health and Safety Code section 125290.40, subdivision (j).

Reference: Sections 125290.30, 125290.40, 125290.55, 125300, Health and Safety Code.

Informative Digest/Policy Statement Overview:

The California Institute for Regenerative Medicine ("Institute" or "CIRM") was established in early 2005 with the passage of Proposition 71 (the "Act"), the California Stem Cell Research and Cures Initiative. The statewide ballot measure, which provides $3 billion in funding for stem cell research and dedicated facilities at California universities and research institutions, was approved by California voters on November 2, 2004, called for the establishment of a new state agency to make grants and provide loans for stem cell research, research facilities and other vital research opportunities.

The Independent Citizens' Oversight Committee ("ICOC") is the 29-member governing board for the Institute. The ICOC members are public officials, appointed on the basis of their experience earned in California's leading public universities, non-profit academic and research institutions, patient advocacy groups and the biotechnology industry.

The mission of the CIRM is to foster and promote stem cell research with the aim of improving human health. A secondary goal is to strengthen California's biotechnology industry and create collateral economic benefits such as high-paying jobs and increased tax revenues. CIRM believes that the funding of commercial research organizations focused on stem cell-related projects is a key component to achieving the overall mission of the Institute. Increased interest by the commercial research sector in stem cell-related research projects and the successful translation of basic research discoveries into commercial products for public use are primary success indicators (among others) that can be used by CIRM to track benefits of commercial sector funding.

Public-private partnerships involving research and development activities among industry, government, and universities can play an instrumental role in introducing key new technologies and valuable products to the commercial marketplace. Experience shows that partnerships involving government participation in research and development activities with industry, universities, and government laboratories can greatly facilitate the translation of basic research discoveries to products with societal benefits.

The proposed regulatory action consolidates the existing regulatory framework that consists of different schemes for non-profit versus for-profit grantees. As stem cell research moves toward the clinic and structures for research proposed by grantees become more complicated, the need to clarify existing regulations has become apparent. For instance, collaborations between and among both non- and for-profit sectors suggest that a single set of regulations will be more user-friendly for our grantees and easier for CIRM to administer. The goal of the consolidation project of existing separate regulations governing non- and for-profit organizations is to harmonize the two into a single set of regulations and better provide greater definition to the scope and application of the policies themselves.

The core principles of the CIRM intellectual property regulations for non-profit and for-profit organizations are unchanged:

1. Ownership: CIRM grantees will own intellectual property that arises from CIRM-funded research activities.

2. Broad Sharing: Intellectual property, including but not limited to data, knowledge, scientific articles, biomedical materials and patented inventions, that are made in the performance of CIRM-funded research will be shared broadly and promptly with the scientific community. This CIRM sharing policy is structured to extend the sharing of CIRM-funded intellectual property beyond practices commonly in use by the scientific community in 2006.

3. Licensing: For patented inventions that are made in the performance of CIRM-funded research, grantee organizations are expected to negotiate non-exclusive licensing agreements where possible except in those circumstances when exclusivity is required to encourage the successful commercial development of the invention into products and

services that can benefit the public. In addition, CIRM has established licensing policies regarding access to resultant therapies and revenue-sharing.

4. March-in rights: Like other funding agencies, CIRM maintains a licensing provision referred to as march-in rights, the purpose of which is to prevent the underutilization of CIRM-funded inventions.

Technical, Theoretical or Empirical Studies, Reports or Documents:

None.

Submittal of Comments:

Any interested party may present comments in writing about the proposed action to the agency contact person named in this notice. Written comments must be received no later than 5:00 p.m. on February 2, 2009. Comments regarding this proposed action may also be transmitted via e-mail to ipregs@cirm.ca.gov or by facsimile transmission to (415) 396-9141.

At this time, no public hearing has been scheduled concerning the proposed regulations. If any interested person or the person's representative requests a public hearing, he or she must do so in writing no later than January 19, 2009.

Effect on Small Business:

CIRM has determined that the proposed regulatory action has no impact on small businesses. The regulations implement conditions on awarding grants for stem cell research. This research is conducted almost exclusively by large public and private non-profit institutions, as well as large for-profit institutions. As such, the regulations are not expected to adversely impact small business as defined in Government Code section 11342.610.

Impact on Local Agencies or School Districts:

CIRM has determined that the proposed regulatory action does not impose a mandate on local agencies or school districts, nor does it require reimbursement by the state pursuant to Part 7 (commencing with section 17500) of Division 4 of the Government Code because the regulatory action does not constitute a "new program or higher level of service of an existing program" within the meaning of section 6 of Article XIII of the California Constitution. CIRM has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action.

Costs or Savings to State Agencies:

CIRM has determined that no savings or increased costs to any agency will result from the proposed regulatory action.

Effect on Federal Funding to the State:

CIRM has determined that no costs or savings in federal funding to the state will result from the proposed regulatory action.

Effect on Housing Costs:

CIRM has made an initial determination that the proposed action will have no effect on housing costs.

Significant Statewide Adverse Economic Impact Directly Affecting Businesses:

CIRM has made an initial determination that adoption of this regulatory action will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California Businesses to compete with businesses in other states.

Cost Impacts on Representative Private Persons or Businesses:

CIRM has made an initial determination that the adoption of these regulations will not have a significant cost impact on representative private persons or businesses. The CIRM is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Impact on the Creation, Elimination, or Expansion of Jobs:

CIRM has determined it is unlikely the proposed regulatory action will impact the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California.

Consideration of Alternatives:

CIRM must determine that no reasonable alternatives considered by the agency, or that have otherwise been identified and brought to the attention of the agency, would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons or businesses than the regulatory action.

Availability of Statement of Reasons and Text of Proposed Regulations:

CIRM has prepared an Initial Statement of Reasons, and has available the express terms of the proposed action, all of the information upon which the proposal is based, and a rulemaking file. A copy of the Initial Statement of Reasons and the proposed text of the regulation may be obtained from the agency contact person named in this notice. The information upon which CIRM relied in preparing this proposal and the rulemaking file are available for review at the address specified below.

Availability of Changed or Modified Text:

After the close of the comment period, CIRM may make the regulations permanent if they remain substantially the same as described in the Policy Statement Overview. If CIRM does make changes to the regulation, the modified text will be made available for at least 15 days prior to adoption. Requests for the modified text should be addressed to the agency contact person named in this notice. CIRM will accept written comments on any changes for 15 days after the modified text is made available.

Agency Contact:

Written comments about the proposed regulatory action; requests for a copy of the Initial Statements of Reasons, the proposed text of the regulation, and a public hearing; inquiries regarding the rulemaking file; and questions on the substance of the proposed regulatory action may be directed to:

C. Scott Tocher, Counsel to the Chair
California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107
(415) 396-9100

These questions may also be addressed to:

Nancy Koch, Counsel
California Institute for Regenerative Medicine
(415) 396-9100

The Notice of Proposed Regulatory Adoption, the Initial Statement of Reasons and any attachments, and the proposed text of the regulations are also available on CIRM's website, www.cirm.ca.gov.

Availability of Final Statement of Reasons:

Following its preparation, a copy of the Final Statement of Reasons mandated by Government Code section 11346.9, subdivision (a), may be obtained from the contact person named above.